



525 Rec'd PCT/PTO 23 OCT 2000

PATENT

ATTORNEY DOCKET NO. 04585/048002

#8

D.J.

12-14-00

Certificate of Mailing: Date of Deposit: October 19, 2000

I hereby certify under 37 CFR 1.8(a) that this correspondence is being deposited with the United States Postal Service as **first class mail** with sufficient postage on the date indicated above and is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

Michelle P. Chicos

Printed name of person mailing correspondence

Michelle P. Chicos

Signature of person mailing correspondence

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Robert N. McBurney et al.

Art Unit:

Serial No.: 09/530,884

Examiner:

Filed: May 5, 2000

Title: THERAPEUTIC METHODS COMPRISING USE OF A
NEUREGULIN

Assistant Commissioner For Patents
Washington, DC 20231

INFORMATION DISCLOSURE STATEMENT

Applicant submits the references listed on the attached form PTO 1449, copies of which are enclosed.

Submission of this statement is not a representation that a search has been made nor is information included in this statement an admission that the information is material to patentability.



This statement is being filed before the receipt of a first Office action on the merits. Please apply any charges or credits to Deposit Account 03-2095.

Respectfully submitted,

Date:

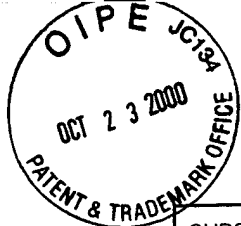
October 19, 2000

Kristina Bieker-Brady, Ph.D.
Reg. No. 39,109

Clark & Elbing LLP
176 Federal Street
Boston, MA 02110
Telephone: 617-428-0200
Facsimile: 617-428-7045



SUBSTITUTE FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE (MODIFIED) PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary) (37 CFR §1.98(b))		Attorney Docket No. 04585/048002 Serial No. 09/530,884 Applicant Robert N. McBurney et al. Filing Date May 5, 2000 Group IDS Filed October 19, 2000
OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)		
	Brockes et al., "The neuron as a source of mitogen: its influence on the proliferation of glial and non-neural cells." <i>In Development in the Nervous System</i> , Garrod and Feldman, pp 309-327 (1980).	
	Canoll et al., "GGF/Neuregulin is a Neuronal Signal that Promotes the Proliferation and Survival and Inhibits the Differentiation of Oligodendrocyte Progenitors." <i>Neuron</i> 17:229-243 (1996).	
	Cheema et al., "Leukemia Inhibitory Factor Prevents the Death of Axotomised Sensory Neurons in the Dorsal Root Ganglia of the Neonatal Rat." <i>J. Neurosci. Res.</i> 37:213-218 (1994).	
	Chen et al., "Expression of Multiple Neuregulin Transcripts in Postnatal Rat Brains." <i>J. Comp. Neurol.</i> 349:389-400 (1994).	
	Curtis et al., "Retrograde axonal transport of ciliary neurotrophic factor is increased by peripheral nerve injury." <i>Nature</i> 365:253-255 (1993).	
	Curtis et al., "Retrograde Axonal Transport of LIF is increased by Peripheral Nerve Injury: Correlation with Increased LIF Expression in Distal Nerve." <i>Neuron</i> 12:191-204 (1994).	
	Danilenko et al., "Neu Differentiation Factor (NDF) Accelerates Epidermal Migration and Differentiation in Excisional Wounds." <i>Faseb J.</i> 8(4-5) A535 (1994).	
	Davis & Stroobant, "Platelet-derived Growth Factors and Fibroblast Growth Factors are Mitogens for Rat Schwann Cells." <i>J. Cell Biol.</i> 110:1353-1360 (1990).	
	Davis et al., "Isolation and characterization of a neu protein-specific activating factor from human ATL-2 cell conditioned medium." <i>Biochem. Biophys. Res. Commun.</i> 179:1536-1542 (1991).	
	Dobashi et al., "Characterization of a neu/c-erbB-2 protein-specific activating factor." <i>Proc. Natl. Acad. Sci. USA</i> 88:8582-8586 (1991).	
	Falls et al., "ARIA, a Protein that Stimulates Acetylcholine Receptor Synthesis, is a Member of the Neu Ligand Family." <i>Cell</i> 72:801-815 (1993).	
	Falls et al., "M, 42,000 ARIA: A Protein that may Regulate the Accumulation of Acetylcholine Receptors at Developing Chick Neuromuscular Junctions." <i>Cold Spring Harb. Symp. Quant. Biol.</i> 55:397-406 (1990).	
	Fann et al., "A Novel Approach to Screen for Cytokine Effects on Neuronal Gene Expression." <i>J. Neurochem.</i> 61:1349-1355 (1993).	
	Funakoshi et al., "Differential Expression of mRNAs for Neurotrophins and their Receptors after Axotomy of the Sciatic Nerve." <i>J. Cell Biol.</i> 123:455-465 (1993).	
	Grinspan et al., "Axonal Interactions Regulate Schwann Cell Apoptosis in Developing Peripheral Nerve: Neuregulin Receptors and the Role of Neuregulins." <i>J. Neurosci.</i> 16:6107-18 (1996).	
	Harris et al., "A prion-like protein from chicken brain copurifies with an acetylcholine receptor-inducing activity." <i>Proc. Natl. Acad. Sci. USA</i> 88:7664-7668 (1991).	
EXAMINER		DATE CONSIDERED
EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant.		

SUBSTITUTE FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE
(MODIFIED) PATENT AND TRADEMARK OFFICEINFORMATION DISCLOSURE
STATEMENT BY APPLICANT
(Use several sheets if necessary)

(37 CFR §1.98(b))

Attorney Docket No.

04585/048002

Serial No.

09/530,884

Applicant

Robert N. McBurney et al.

Filing Date

May 5, 2000

Group

IDS Filed

October 19, 2000

U.S. PATENTS

Examiner's Initials	Patent Number	Issue Date	Patentee	Class	Subclass	Filing Date (If Appropriate)
	5,082,670	01/21/92	Gage et al.			
	5,399,346	03/21/95	Anderson et al.			
	5,367,060	11/22/94	Vandlen et al.			
	5,237,056	08/17/93	Fischbach et al.			
	5,602,096	02/11/97	Goodearl et al.			
	5,530,109	06/25/96	Goodearl et al.			

FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION

	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation (Yes/No)
	WO 92/20798	11/26/92	PCT			
	EP 0 505 148 A1	09/23/92	Europe			
	WO 92/12174	07/23/92	PCT			
	WO 91/18921	12/12/91	PCT			
	WO 91/15230	10/17/91	PCT			
	WO 94/00140	01/06/94	PCT			
	WO 94/04560	03/03/94	PCT			
	WO 94/08007	04/14/94	PCT			
	WO 94/03644	02/17/94	PCT			

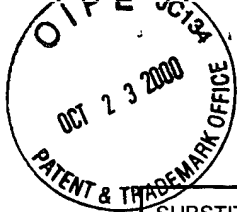
OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)

	Acsadi et al., "Human dystrophin expression in mdx mice after intramuscular injection of DNA constructs." <i>Nature</i> 352:815-818 (1991).
	Benveniste et al., "Purification and characterization of a human T-lymphocyte-derived glial growth-promoting factor." <i>Proc. Natl. Acad. Sci. USA</i> 82:3930-3934 (1985).
	Brockes et al., "Assay and Isolation of Glial Growth Factor from the Bovine Pituitary." <i>Meth. Enz.</i> 147:217-225 (1987).

EXAMINER

DATE CONSIDERED

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant.



SUBSTITUTE FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE (MODIFIED) PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary) (37 CFR §1.98(b))	Attorney Docket No.	04585/048002
	Serial No.	09/530,884
	Applicant	Robert N. McBurney et al.
	Filing Date	May 5, 2000
	Group	
	IDS Filed	October 19, 2000

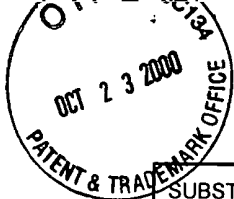
OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)

	Hefti, "Neurotrophic Factor Therapy for Nervous System Degenerative Diseases." <i>J. Neurobiol.</i> 25:1418-1435 (1994).
	Henderson et al., "GDNF: A Potent Survival Factor for Motoneurons Present in Peripheral Nerve and Muscle." <i>Science</i> 266:1062-1064 (1994).
	Holmes et al., "Identification of Heregulin, a Specific Activator of p ^{185erbB2} ." <i>Science</i> 256:1205-1210 (1992).
	Huang et al., "Purification and Characterization of the neu/erb B2 Ligand-Growth Factor from Bovine Kidney." <i>J. Biol. Chem.</i> 267:11508-11512 (1992).
	Hughes et al., "Members of Several Gene Families Influence Survival of Rat Motoneurons In Vitro and In Vivo." <i>J. Neurosci. Res.</i> 36:663-671 (1993).
	Kimura et al., "Structure, expression and function of a schwannoma-derived growth factor." <i>Nature</i> 348:257-260 (1990).
	Kotzbauer et al., "Postnatal Development of Survival Responsiveness in Rat Sympathetic Neurons to Leukemia Inhibitory Factor and Ciliary Neurotrophic Factor." <i>Neuron</i> 12:763-773 (1994).
	Lillien & Raff, "Differentiation Signals in the CNS: Type 2 Astrocyte Development In Vitro as a Model System." <i>Neuron</i> 5:111-119 (1990).
	Lin et al., "GDNF: A Glial Cell Line-Derived neurotrophic Factor for Midbrain Dopaminergic Neurons." <i>Science</i> 260:1130-1132 (1993).
	Lupu et al., "Direct Interaction of a Ligand for the <i>erbB2</i> Oncogene Product with the EGF Receptor and p ^{185erbB2} ." <i>Science</i> 249:1552-55 (1990).
	Lupu et al., "Characterization of a growth factor that binds exclusively to the <i>erbB-2</i> receptor and induces cellular responses." <i>Proc. Natl. Acad. Sci. USA</i> 89:2287-2291 (1992).
	Mahanthappa et al., "Glial Growth Factor 2, a Soluble Neuregulin, Directly Increases Schwann Cell Motility and Indirectly Promotes Neurite Outgrowth." <i>J. Neurosci.</i> 16:4673-4683 (1996).
	Marchionni et al., "Glial growth factors are alternatively spliced <i>erbB2</i> ligands expressed in the nervous system." <i>Nature</i> 362:312-318 (1993).
	Martinou et al., "Cholinergic Differentiation Factor (CDF/LIF) Promotes Survival of Isolated Rat Embryonic Motoneurons In Vitro." <i>Neuron</i> 8:737-744 (1992).
	Mitsumoto et al., "Arrest of Motor Neuron Disease in <i>wobbler</i> Mice Cotreated with CNTF and BDNF." <i>Science</i> 265:1107-1110 (1994).
	Mudge, "New ligands for Neu?" <i>Current Biol.</i> 3:361-64 (1993).
	Nishi, "Neurotrophic Factors: Two are Better than One." <i>Science</i> 265:1052-53 (1994).
	Oppenheim et al., "Developing motor neurons rescued from programmed and axotomy-induced cell death by GDNF." <i>Nature</i> 373:344-346 (1995).

EXAMINER

DATE CONSIDERED

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant.



SUBSTITUTE FORM PTO-1449 (MODIFIED)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		Attorney Docket No.	04585/048002
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary) (37 CFR §1.98(b))				Serial No.	09/530,884
				Applicant	Robert N. McBurney et al.
				Filing Date	May 5, 2000
				Group	
				IDS Filed	October 19, 2000
OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)					
	Peles & Yarden, "Neu and its Ligands: From an Oncogene to Neural Factors." <i>Bio Essays</i> 15:815-824 (1993).				
	Peles et al., "Isolation of the Neu/HER-2 Stimulatory Ligand: A 44kd Glycoprotein that Induces Differentiation of Mammary Tumor Cells." <i>Cell</i> 69:205-216 (1992).				
	Pinkas-Kramarski, "Brain neurons and glial cells express Neu differentiation factor/heregulin: A survival factor for astrocytes." <i>Proc. Natl. Acad. Sci. USA</i> 91:9387-9391 (1994).				
	Rosenbaum et al., "Schwann Cells Express NDF and SMDF/n-ARIA mRNAs, Secrete Neuregulin, and Show Constitutive Activation of erbB3 Receptors: Evidence for a Neuregulin Autocrine Loop." <i>Ex. Neurol.</i> 148:604-615 (1997).				
	Syroid et al., "Cell death in the Schwann cell lineage and its regulation by neuregulin." <i>Proc. Natl. Acad. Sci. USA</i> 93:9229-9234 (1996).				
	Trachtenberg et al., "Schwann cell apoptosis at developing neuromuscular junctions is regulated by glial growth factor." <i>Nature</i> 379:174-177 (1996).				
	Usdin & Fischbach, "Purification and Characterization of a Polypeptide from Chick Brain that Promotes the Accumulation of Acetylcholine Receptors in Chick Myotubes." <i>J. Cell Biol.</i> 103:493-507 (1986).				
	Verdi et al., "A Reciprocal Cell-Cell Interaction Mediated by NT-3 and Neuregulins Controls the Early Survival and Development of Sympathetic Neuroblasts." <i>Neuron</i> 16:515-527 (1996).				
	Wen et al., "Neu Differentiation Factor: A Transmembrane Glycoprotein Containing an EGF Domain and an Immunoglobulin Homology Unit." <i>Cell</i> 69:559-572 (1992).				
	Wolswijk, "Chronic Stage Multiple Sclerosis Lesions Contain a Relatively quiescent Population of Oligodendrocyte Precursor Cells." <i>J. Neurosci.</i> 18:601-609 (1998).				
	Xie et al., "Rapid, Small-Scale RNA Isolation from Tissue Culture Cells." <i>Biotechniques</i> 11:325-327 (1991).				
	Yamamori et al., "The Cholinergic Neuronal Differentiation Factor from Heart Cells is Identical to Leukemia Inhibitory Factor." <i>Science</i> 246:1412-1416 (1989).				
	Yan et al., "In vivo neurotrophic effects of GDNF on neonatal and adult facial motor neurons." <i>Nature</i> 373:341-344 (1995).				
	Yarden & Ullrich, "Growth Factor Receptor Tyrosine Kinases." <i>Annu. Rev. Bioch.</i> 57:443-478 (1988).				
	Yarden & Peles, "Biochemical Analysis of the Ligand for the neu Oncogenic Receptor." <i>Biochemistry</i> 30:3543-3550 (1991).				
	Yuen et al., "Therapeutic Potential of Neurotrophic Factors for Neurological Disorders." <i>Ann. Neurol.</i> 40:346-354 (1996).				
	Yin et al., "Cell Death of Spinal Motoneurons in the Chick Embryo following Deafferentation: Rescue Effects of Tissue Extracts, Soluble Proteins, and Neurotrophic Agents." <i>J. Neurosci.</i> 14:7629-7640 (1994).				
EXAMINER			DATE CONSIDERED		
EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant.					